REMARKS

Claims 1-32 are pending in the subject application. Applicants have amended claims 1-3, 5, 8, 14-15, 17-19, 21, 24, and 30-32 in order to make certain formatting changes. In addition, applicants have amended the specification to include references to SEQ ID NOs. Applicants maintain that the amendments to the claims and the specification do not introduce an issue of new matter. Accordingly, claims 1-32 will still be pending and under examination upon entry of this Amendment.

In view of the arguments below, applicants maintain that Examiner's rejections have been overcome and respectfully request that they be withdrawn.

Formalities

Claim Objections

The Examiner objected to claims 1-32 as allegedly containing certain informalities. In response, applicants have amended the claims, and amended claims 1-32 do not contain the informalities objected to by the Examiner.

Sequence Listing

The Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures, attached hereto as Exhibit A, requires that applicants submit a paper copy and computer readable form of a Sequence Listing, along with a Statement under 37 C.F.R. §1.821(f). Accordingly, applicants hereby submit a Sequence Listing, attached hereto as Exhibit B, in compliance with the

requirements of §1.821-1.825. In addition, applicants submit herewith the Sequence Listing on the enclosed computer diskette. Applicants also submit as Exhibit C a Statement In Accordance With 37 C.F.R. §1.821(f) certifying that the contents of the computer readable form and paper copy are the same, and raise no issue of new matter. In addition, the specification has been amended to contain appropriate references to SEQ ID NOs.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-32 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner objects to certain phrases and terms as recited in the claims.

In response, but without conceding the correctness of the Examiner's rejection, applicants note that claims 1-32 do not recited the phrases and terms objected to by the Examiner.

In view of the above remarks, applicants maintain that claims 1-32 satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-32 under 35 U.S.C. §112, first paragraph, as allegedly not enabled.

In response, applicants respectfully traverse the Examiner's rejection.

The test for enablement is whether one skilled in the art could, at the time of the invention, make and use the claimed invention

based on the disclosure and information known in the art without undue experimentation. Applicants maintain that the claimed invention satisfies the test for enablement, and that the Examiner has not set forth sufficient grounds for concluding otherwise.

Briefly, the rejected claims provide methods of delivering an antigen to a Class I MHC receptor to induce immunity against the antigen in a subject having a disease wherein the antigen is associated with the presence of the disease in the subject. The claimed invention is based on applicants' surprising discovery that antigen-filled particles will bind to ligand-binding antigen-presenting cells (APCs), permitting the APC phagolysomes to ingest the Ag-particles to facilitate transfer of the ingested antigen from the phagolysomes into the cytoplasm.

In support of the rejection, the Examiner asserts that applicants have provided insufficient guidance and direction regarding the effectiveness of any of the recited administered cells in delivering an antigen to a Class I MHC receptor to induce immunity against the antigen in a subject. Specifically, the Examiner asserts that the state of the art is unpredictable and applicants have not disclosed working examples that provide evidence which is reasonably predictive of the claimed methods' being effective in inducing a cytotoxic response to an antigen *in vivo*. In support of the rejection, the Examiner cites Grufman et al., Sala et al. (2001 reference), and Sala et al. (2002 reference).

Applicants disagree with the Examiner's position. First with regard to the Examiner's statement concerning an alleged "unpredictability" in the art, applicants maintain that the specification discloses a working example showing that

applicants' invention works. That is, the specification discloses a procedure for the loading of a peptide into red blood cell ghosts; delivery of the peptide to a Class I MHC receptor; and subsequent induction of cytotoxic CD8 lymphocytes. Such teaching can be found at, *inter alia*, pages 32-35 of the specification. The Examiner's reliance on the cited references does not support the Examiner's position that the specification does not enable the claims or that the state of the art is unpredictable. In addition, applicants submit that none of the references cited by the Examiner describes experiments whose outcomes can be used to predict the outcome of applicants' invention. Therefore, the references do not provide a teaching that indicated that applicants' invention does not work.

In view of the above remarks, applicants respectfully request that the Examiner withdraw the rejection of claims 1-32 under 35 U.S.C. §112, first paragraph.

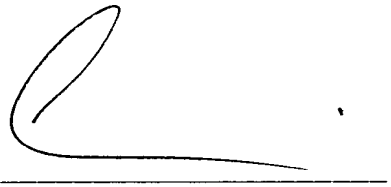
Conclusion

Applicants maintain that claims 1-32 are in condition for allowance, and thus, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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Registration No. 28,678
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Attorneys for Applicants
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

9/ec/03

Alan J. Morrison Date
Reg. No. 37,399

EXHIBIT A

Application No.: 09/658,698

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An Initial ~~or substitute~~ computer readable form (CRF) copy of the "Sequence Listing".
- [X] An Initial ~~or substitute~~ paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE

COPY FOR [ ] File [X] Applicant

EXHIBIT B

SEQUENCE LISTING

<110> Silverstein, Samuel C.
Loike, John D.
Divirgilio, Francesco

<120> A Novel Method For Using Phagocytic Particles And ATP Receptors To Deliver Antigens To MHC Class I Receptors To Induce Immunity Against Microbial Pathogens Or Tumors Or To Suppress Immunity

<130> 0575-60467

<140> 09/658,698
<141> 2000-09-08

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EXHIBIT C

Dkt. 60467/JPW/AJM/HA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Samuel C. Silverstein et al.

Serial No.: 09/658,698 Examiner: Amy M. DeCloux

Filed : September 8, 2000 Group Art Unit: 1644

For : A NOVEL METHOD FOR USING PHAGOCYTIC PARTICLES AND ATP RECEPTORS TO DELIVER ANTIGENS TO MHC CLASS I RECEPTORS TO INDUCE IMMUNITY AGAINST MICROBIAL PATHOGENS OR TUMORS OR TO SUPPRESS IMMUNITY

1185 Avenue of the Americas
New York, NY 10036
September 26, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

STATEMENT IN ACCORDANCE WITH 37 C.F.R. §1.821(f)

In accordance with 37 C.F.R. §1.821(f), I hereby certify that the computer readable form containing the nucleic acid and/or amino acid sequences required by 37 C.F.R. §1.821(e) and submitted in connection with the above-identified application, has the same information as the pages attached hereto as **Exhibit B** and entitled ''Sequence Listing'', and contains no new matter.

Respectfully submitted,

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